UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/842,148	04/26/2001	Chester Struble	P-9440	6240

27581 7590 12/23/2003

MEDTRONIC, INC.
710 MEDTRONIC PARKWAY NE
MS-LC340
MINNEAPOLIS, MN 55432-5604

EXAMINER	
SCHAETZLE, KENNEDY	
ART UNIT	**PAPER NUMBER**
3762	

DATE MAILED: 12/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/842,148	STRUBLE, CHESTER
	Examiner	Art Unit
	Kennedy Schaetzle	3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 October 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 13-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 13-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 April 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 102/103

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 17-20, 22, 35 and 37-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Cohen.

The application of Cohen to claims 17, 35 and 40 parallels the rejection of claim 1 as set forth below.

Regarding claim 18, the drug delivery system of Cohen is configured to stand idle when the arrhythmia signal is indicative of unstable SVT or unstable VT, or AF or VF as indicated in Figs. 5.

4. Claims 1-8, 10, 11, 13-16, 21, 23-27, 29-31 and 36 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Cohen (Pat. No. 5,156,148).

Regarding claim 1, Cohen disclose a system for treating cardiac arrhythmia comprising a sensing lead (note col. 8, lines 38-46), a processor configured to receive the electrical signals and to detect and discriminate between atrial and ventricular arrhythmias and generate an arrhythmia signal (note the paragraph abridging cols. 4 and 5, and col. 10, lines 43-55), a drug delivery system 18 configured to receive the arrhythmia signal comprising a first drug pump (e.g., element 18a) containing a first drug (note col. 7, lines 29-37 and the various drugs mentioned throughout Figs. 5A-5I),

a second drug pump (e.g., element 18b) containing a second drug (again note the various drugs mentioned in the above recited figures), and first and second infusion apparatus coupled to the first and second drug pumps (the venous and/or arterial injection devices discussed in Fig. 2). The drug delivery system is configured to activate the first drug pump to dispense the first drug via the first infusion apparatus when the arrhythmia signal is indicative of atrial arrhythmia (see for example boxes 547 and 550 of Fig. 5C), and is configured to activate the second drug pump to dispense the second drug via the second infusion apparatus when the arrhythmia is indicative of ventricular arrhythmia (see for example boxes 503 and 510 of Fig. 5B).

Regarding the use of first and second drugs, Cohen teaches that the system may employ drug(s) (note plural form) and that the various arrhythmias may be treated singly or in *combination* (col. 7, lines 18-37). Most assuredly if one was to implement the treatment defined by the flowcharts of Figs. 5A-5I which call for a variety of different drugs to be used depending upon the particular heart condition detected, one would necessarily have to provide at least first and second drug pumps containing respective first and second drugs.

Regarding the use of a sensing lead, although the examiner considers conventional EKG electrodes such as discussed by Cohen and referred to above, to pertain to leads (the examiner notes that a variety of artisans equate the term "electrodes" to the term "leads" even though such a comparison is not entirely accurate), those of ordinary skill in the art would have seen the provision of a lead or leads to obtain EKG signals for a device of the type shown in Fig. 7 to be blatantly obvious given their ubiquitous nature in implantable medical devices.

Regarding claim 4, note the atrial and ventricular channels shown in Fig. 2 that carry the electrical heart signal to the processing device. Although Cohen does not explicitly state that the atrial (or ventricular) signal is obtained from a lead located in the atrium (or ventricle), the use of an atrial lead and a ventricular lead to respectively obtain an atrial signal and a ventricular signal would clearly have been considered blatantly obvious by anyone of ordinary competence in the art, especially given that this type of arrangement is old and conventional.

Regarding claim 5, the examiner considers the CPU 13 to comprise both a processor and a controller, with the control signal being input to the various drug delivery devices 18a-18d.

Concerning claim 7, the monitor/recorder is considered to represent an input/output device (note col. 7, lines 38-43).

In reference to claim 8, the examiner considers drug delivery devices 18a-18d to represent at least four drug pumps. Again, since more than three different types of drugs have been disclosed by Cohen as available for use with the invention depending on the situation encountered, it would have been inherent that one of the drug pumps 18 would have contained a third drug.

Concerning claim 10, note box 510 of Fig. 5B.

The rejection of independent claims 11 and parallel the rejection of claim 1 above.

In reference to claim 13, the examiner considers the device of Cohen to inherently select first and second dosages of first and second drugs if it is to perform the method set forth in Fig. 5, since it would be unethical to implant a selective drug delivery device in a patient without any control whatsoever over the dosage of drug released. In any event, the examiner took Official Notice in the previous Office Action that the selection of drug dosages and the subsequent dispensing of said dosages into the body is an old and well-known technique to deliver proper, safe and effective amounts of medication. Since the applicant has not timely traversed this Notice, the feature is considered to be admitted prior art.

Regarding claim 14, the examiner considers the gravity operated drug delivery system discussed by Cohen to be a drip dosage mechanism. In any event, those of ordinary skill in the art would have seen the particular method for drug delivery to be a matter of obvious design. Since drip and bolus dosage drug delivery techniques are clearly known by those of ordinary skill in the art, the final decision as to which system to employ rests in the hands of the system designer and is dependent upon the application at hand.

Concerning claims 15, 25 and 26, the examiner considers the device of Cohen to dispense a bolus of a first drug in view of the fact that Webster's dictionary defines a "bolus" as simply a mass injected into a blood vessel. In any event, the particular form of the medicament injected would have been considered a matter of obvious design dependent upon the particular drug employed and the relative effectiveness of the various known delivery mechanisms.

In regards to the drug pump activating and defibrillation steps set forth in claims 15, 25 and 26, Cohen explicitly teaches that one may apply defibrillation shocks to revert cardiac arrhythmias as is old and well-known in the art. The particular steps need not be taken in any particular order or timing sequence, and therefore any prior art method comprising these steps would read on the claim. In any event, the examiner considers the exact treatment regimen to be a physician's prerogative.

Regarding claim 16, the comments made immediately above apply here as well.

With respect to claims 21 and 36, again as recited above, regarding the use of a sensing lead, although the examiner considers conventional EKG electrodes such as discussed by Cohen and referred to above, to pertain to leads (the examiner notes that a variety of artisans equate the term "electrodes" to the term "leads" even though such a comparison is not entirely accurate), those of ordinary skill in the art would have seen the provision of a lead or leads to obtain EKG signals for a device of the type shown in Fig. 7 to be blatantly obvious given their ubiquitous nature in implantable medical devices.

5. Claims 9, 28 and 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen.

Regarding claim 9, Cohen does not explicitly refer to the use of a first drug selected from the group consisting of digitalis and beta blockers. Clearly the decision as to which particular medication should be used in the treatment of the patient would reside with the patient's physician, as the physician is in the best position to ascertain the condition of the patient. Those of ordinary skill in the art would have therefore considered the exact drug to be employed from the list of known anti-arrhythmia drugs to be an obvious physician's prerogative.

Concerning claim 28, although Cohen does not elaborate on the specific site for drug infusion, Fig. 2 clearly indicates that the drugs may be infused by veineous and/or arterial injection devices. Obviously then, the subclavian vein and the superior vena cava qualify as a suitable sites for the practice of the Cohen invention. The particular location for injection would have ultimately been considered a matter best decided by the patient's physician and clinical data indicating the most efficacious site for the situation at hand.

Regarding claim 32, while Cohen does not explicitly discuss programming criteria such as minimum dosage, maximum dosage and frequency of administration, it is taught that the device may be programmed via a wireless link to access to the RAM/ROM so as to alter a variety of baselines and patient treatment regimes (note for example the text abridging cols. 8 and 9). The examiner took Official Notice in the prior Office Action that the programming of dosages and the frequency of administration of such dosages are old and well-known parameters used to modify patient treatment regimes. Obviously one must be permitted to adjust these parameters as patient condition changes for ethical and efficacious treatment. Since the applicant has not timely traversed this Notice, the feature is considered to be admitted prior art.

Concerning claims 33 and 34, Cohen does not disclose refilling the various reservoirs containing the treatment drugs. The examiner took Official Notice in the previous Office Action that refilling drug reservoirs as needed to maintain effective treatment is old and well-known in the art. The use of a needle and syringe to resupply an implantable drug delivery device is also considered to be old and well-known by those of ordinary competence in the art --Official Notice was also taken in the previous Office Action. Since the applicant has not timely traversed this Notice, the feature is considered to be admitted prior art.

Response to Arguments

1. Applicant's arguments filed October 7, 2003 have been fully considered but they are not persuasive. The applicant argues that Cohen does not determine whether an arrhythmia is atrial or ventricular as a function of the sensed cardiac signals, but rather

identifies atrial and ventricular arrhythmias as a function of both a physiologic signal and a cardiac electrical signal. The present claims, however, do not preclude determination of atrial and ventricular arrhythmias as a function of more than one variable. A system that is a function of *x* and *y* is still a system that is a function of *x*. As such, the rejection stands.

Conclusion

2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 703 308-2211. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0858.

KJS
December 14, 2003

KENNEDY SCHAETZLE
PRIMARY EXAMINER